IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ashley J. Birkett) PATENT)

Serial No.: 09/930,325) Attorney Docket | ICC-103.1 |

Filed: August 15, 2001) (4564-83502) |

For: MALARIA IMMUNOGEN AND VACCINE) | Group Art Unit: | 1614 |

Examiner:)

INFORMATION DISCLOSURE STATEMENT

BOX IDS Commissioner For Patents Washington, D.C. 20231 DEC 0 9 2002
Technology Center 2100

Sir:

Pursuant to 37 C.F.R. §1.97, Documents A1-A67 are listed on the attached Form PTO-1449. Documents A1-A4, A14-A61 were disclosed and discussed in the text of the subject patent application; whereas Documents A6-A8, A10-A11, A62-A63, and A65-A67 were subsequently located and are therefore provided herewith. Document A5, an issued U.S. patent, and Document A9, its published PCT counterpart, describe an invention of the present inventor that relates to a hepatitis B core-based vaccine. Document A12 is a published PCT application of the present inventor that discloses stabilized hepatitis B core-based vaccines. Document A13 is the published PCT version of the subject application.

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Documents A42, A56 and A65-A66 were cited in the

International Search Report (copy enclosed) for Document A13

(PCT Application WO 02/13765), corresponding to the present application. Document A64 is a poster presented by the inventor and co-workers in October of 1999 of results using vaccine candidates. None of these cited documents disclose, enable or teach claimed subject matter of the present invention.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as

defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

If any fees or petition are believed to be necessary, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

Respectfully submitted

(/)

rene M. Reininger, Reg. No. 48,439

September 10, 2002

Enclosures:

Form PTO-1449, PCT Search Report Documents A1-A11 in Binder 1 of 3 Documents A12-A25 in Binder 2 of 3 Documents A26-A67 in Binder 3 of 3

Welsh & Katz, Ltd. 22nd Floor 120 South Riverside Plaza Chicago, Illinois 60606 312/655-1500

No

Sheet 1 of 3 Atty. Docket No. (Rev. 5/92) U.S. Department of Commerce ICC-103.1 Comparable to Patent and Trademark Office (4564-83502) 02 SEP 12 AM 10: 33 Form PTO-1449 Applicants INFORMATION DISCLOSURE CITATION Ashley J. Birkett (Use several sheets if necessary) Filing Date Group August 15, 2001 U.S. PATENT DOCUMENTS Filing Date *Examiner Subclass If Appropriate Initial Document Number Date Name Class 88 424 Αl 4,818,527 04/1989 Thornton, et al. 11/1989 424 4,882,145 Thornton, et al. A2 A3 5,143,726 09/1992 Thornton, et al. 424 88 5,928,902 07/1999 DeWilde, et al. 435 693 A4 189.1 A5 6,231,864 5/15/01 Birkett 424 Colman, et la. 424 191.1 5,614,194 3/25/97 Α6 12/12/89 Good, et al. 514 12 Α7 4,886,782 FOREIGN PATENT DOCUMENTS Translation Country Class Subclass Yes Document Number Date WO 01/983333 • 12/27/01 **PCT** A8 WO 99/40934 8/19/99 PCT A9 RECEIVED WO 00/32625 ¢ 6/8/2000 PCT A10 DEC 0 \$ 2002 WO 01/27821 o 4/19/2001 **PCT** A11 WO 02/14478 2/21/2002 **PCT** A12 Technology Center 2100 WO 02/13765 2/21/2002 **PCT** A13 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) A14 Marlar, T., et al., Trans. R. Soc. Trop. Med. Hyg., (1995) 89(3): p. 307-308 6 Garg et al., Trans. R. Soc Trop. Med. Hyg., (1995) 89(6): p. 656-657 A15 Baird et al., Am. J. Trop. Med. Hyg., (1991) 44(5): p. 547-552 A16 A17 Baird et al., Trans R Soc Trop Med Hyg, (1996) 90(4): p. 409-411 & Baird et al., J. Infect. Dis., (1995) 171(6): p. 1678-1682 A18 Murphy et al., Lancet, (1993) 341(8837): p. 96-100 . A19 A20 Schwartz et al., [letter]. N. Engl. J. Med., (1991) 324(13): p. 927

Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not *Examiner: considered. Include copy of this form with next communication to applicant.

Schuurkamp et al., Trans. R. Soc. Trop. Med. Hyg., (1992) 86(2): p. 121-122

Charoenlarp et al., Southeast Asian J. Trop. Med. Public Health, (1973) 4(1): p. 135-137 6

Rieckmann et al., Lancet, (1989) 2(8673): p. 1183-1184

Krotoski, [letter]. N. Engl. J. Med., (1980) 303(10): p. 587

Good, et al., Anu. Rev. Immunol., (1998) 16: p. 57-87 💘

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Examiner

(Rev. 5/92) Comparable to Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. ICC-103.1 (4564-83502)	Serial No. 09/930,325		
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)			Applicants Ashley J. Birkett			
			Filing Date August 25, 2001	Group		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	A26 Clyde et al., Am. J. Med. Sci., (1973) 266(6): p. 398-403					
	A27	Rieckmann et al., Trans. R. Soc. Trop. Med. Hyg., (1974) 68(3): p. 258-259				
	A28	Zavala et al., Science, (1985) 228(4706): p. 1436-40				
	A29	Nussenzweig et al., Ciba Found. Symp., (1986) 119: p. 150-163				
	A30	Etlinger et al., Immunology, (1988) 64(3): p. 551-558				
	A31	Etlinger et al., J. Immunol., (1988) 140(2): p. 626-633 •				
	A32	Herrington et al., Nature, (1987) 328(6127): p. 257-259				
	A33	Ballou et al., Lancet, (1987) 1(8545): p. 1277-1281				
	A34	Ballou et al., Nature, (1987) 328(6127): p. 237-239 Ballou et al., Lancet, (1987) 1(8545): p. 1277-1281 Good et al., Science, (1987) 235(4792): p. 1059-62 Calvo-Calle et al., J. Immunol., (1993) 150(4): p. 1403-1412 Moreno et al., Int. Immunol., (1991) 3(10): p. 997-1003 Stoute et al., N. Engl. J. Med., (1997) 336(2): p. 86-91				
	A35	Calvo-Calle et al., J. Immunol., (1993) 150	0(4): p. 1403-1412 • Techn	2002		
	A36	Moreno et al., Int. Immunol., (1991) 3(10): p. 997-1003				
	A37	Stoute et al., N. Engl. J. Med., (1997) 336(2): p. 86-91				
	A38	Stoute et al. J. Infect Dis. (1998 Oct) 178(4):1139-44				
	A39	Milich et al., Science, (1986) 234(4782): p. 1398-1401				
	A40	Herrington et al., Am J Trop Med Hyg. (1991) 45(6): p. 695-701				
	A41	Schodel et al., Behring Inst. Mitt. (1997) (98): p. 114-119				
	A42	Schodel et al., J. Exp. Med. (1994) 180(3): p. 1037-46				
	A43 Pumpens et al., Intervirology (1995) 38:63-74 C					
	A44 Metzger et al., J. Gen. Viol. (1998) 79 :587-590 •					
	A45	Hoffman et al., Nat. Med. (1997) 3(1):80-83				
	A46	Conway et al., <i>Nature</i> , (1997) 386 :91-94				
	A47	Bottcher et al., Nature, (1997) 386:88-91				
	A48	Zheng et al., J. Biol. Chem., (1992) 267(13):9422-9429				
	A49	Birnbaum et al., J. Virol. (1990) 64, 3319-3330 *				
	A50	Clarke et al., F. Brown et al. eds. Vaccines (1991) 91, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, pp.313-318				
Examiner			Date Considered			
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

(Rev. 5/92) Comparable to Form PTO-144)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. ICC-103.1 (4564-83502)	Serial No. 09/930,325		
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	A51	Seifer et al., Intervirology (1995) 38:47-62				
	A52	Gallina et al. J. Virol. (1989) 63:4645-4652	. •	Δ.		
	A53	Inada et al. Virus Res., (1989) 14:27-48		TECK!		
	A54	Maassen et al. Arch. Virol. (1994) 135:131	-142 0	DEC VED		
	A55	Schodel et al. Infect. Immunol. (1994) 62:1	1669-1676	2002		
	A56	Gallina et al. J. Virol. (1989) 63:4645-4652 Inada et al. Virus Res., (1989) 14:27-48 Maassen et al. Arch. Virol. (1994) 135:131-142 Schodel et al. Infect. Immunol. (1994) 62:1669-1676 Ulrich et al. Adv. Virus Res. Vol. 50 (1998) Academic Press pages 141-182 Qari et al. Lancet (1993) 341(8848):780-783				
	A57	Qari et al. Lancet (1993) 341(8848):780-783				
	A58	Moreno et al. J. Immunol. (1993) 151(1): 489-499 •				
	A59	Hoffman et al. Malaria Vaccine Development, Chapter 3: Attacking the Infected Hepatocyte, 1996 American Society for Microbiology, Washington, D.C.				
,	A60	Calvo-Calle et al. J. Immunol. (1997) 159(3): p. 1362-1373				
	A61	Coatney et al. (1962) 9:285-292				
	A62	Krüger et al. Biol. Chem. (1999) 380:275-276 •				
	A63	Nardin et al. J. Exp. Med. (1982) 156:20-30				
	A64	Poster presented by J. Haron at the Center for Advanced Technology and Medicine (CABM) Symposium, Rutgers University Medical Center on October 13-14, 1999				
	A65	Isaguliants et al. Immunol. Ltr. (1996) 42:173-178				
	A66	Schodel et al. J. Biotechnol. (1996) 44:91-96				
	A67	Wynne et al., Mol. Cell (June 1999) 3:771-780 6				
	_					
Examiner			Date Considered			
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						